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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968
7590 HOVEY, WILLIAMS, TIMMONS & COLLINS Suite 400 2405 Grand Kansas City, MO 64108			EXAMINER HORNING, MICHELLE S	
			ART UNIT 1648	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/06/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/051,253	STOUT, ROBERT L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 January 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3,4,8-12,15-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3, 4, 8-12, 15-19 and 21-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This office action is responsive to communication filed 1/19/2007. The claims under current examination are as follows: claims 3, 4, 8-12, 15-19 and 21-25. Claims 1, 2, 5-7, 13-14, 20-21 and 26-30 have been canceled.

The following rejection from the previous office action is withdrawn, not because the Applicants' arguments were found to be persuasive, but because of the grounds for more applicable rejections (see new rejections below). More specifically, the art teaches that active acute HCV results in high titer of HCV antibodies.

1. 35 USC 103 in view of Houghton et al, Teo et al and Lazizi et al.

### ***New Rejections***

#### **35 U.S.C. 112, 1<sup>st</sup> paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 3, 4, 8-12, 15-19 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

*Nature of the invention.* The claims are drawn to a method of predicting whether an individual has a chronic HCV infection with 80% accuracy.

*State of the art.* At the time the invention was made, it was well known that serum IgM antibodies to HCV is found in active HCV infections, including both acute and chronic HCV. The prior art also teaches that the presence of such antibodies cannot determine whether the individual has recovered from the infection or is still carrying the virus. Further, the prior art teaches that in order to confirm that an HCV infection is indeed active, PCR techniques can be employed to amplify and detect serum HCV RNA. See Brillanti et al 1993.

*Breadth of the claims.* The claims are limited to predicting the probability that one has chronic HCV.

*Working examples.* The specification provides data that compare the optical density measurements for HCV antibody and HCV RNA test to suggest a correlation between the two measurements for predictability (page 13). Table 3 (page 15) shows the OD readings of samples against their PCR HCV RNA levels, including undetectable and detectable levels. It is further noted that the specification provides no support for any method with 80% accuracy, more specifically for chronic HCV infection.

*Guidance in the specification.* The specification provides no guidance in predicting the how the method can be made/used in distinguishing between a chronic HCV infection and an active acute HCV infection. More specifically, no antibody assays or OD measurements are described that would allow an artisan to distinguish one infection from the other. The specification does, however, describe a method in

qualitatively predicting whether one has an HCV infection or not. Of note, the specification hardly refers to acute HCV.

*Predictability of the art.* There is no way one could successfully predict whether one has a chronic HCV infection based on the claimed method. The prior art recites the following: "In patients with chronic HCV infection, different figures of IgM anti-HCV positivity were reported" and "there was a high prevalence of IgM antibodies to the core HCV antigen in patients with acute hepatitis C" (Brillanti et al, page 215). Thus, for both types of infections, the samples would test positive for HCV antibodies and have a higher OD reading compared to a sample in which the individual has recovered from the infection.

*Amount of experimentation necessary.* Much experimentation is still required in order to predict the probability that one specifically has a chronic HCV infection as claimed. The specification discloses a method that qualitatively determines whether the virus is present or not (that is, by determining the OD readings of antibody in the sample following antibody assays). There is no step that distinguishes and thus, predicts chronic HCV from acute HCV. All of the work is left for others to do.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

**Claims 3, 4, 8-12, 15-19 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a**

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention is drawn to a method of predicting chronic HCV infection in an individual via an antibody assay with HCV antigens and OD readings. While it is known that such antibodies are found in individuals with HCV infections as well as those who have recovered from the infection, the specification does not describe how the OD readings of such antibodies can specifically predict chronic HCV with 80% accuracy or even distinguish from those who have acute HCV. Thus, the above claims are rejected.

## **CONCLUSION**

No claim is allowed.

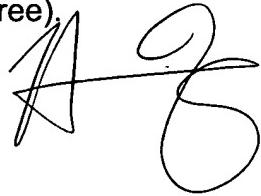
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at  
866-217-9197 (toll-free).

  
Michelle Horning  
Patent Examiner





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SUPERVISORY PATENT EXAMINER  
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